IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

K & S ASSOCIATES, INC.,)
Plaintiff,)
v.) Case No
AMERICAN ASSOCIATION OF PHYSICISTS IN MEDICINE,)))
Defendant.)

VERIFIED COMPLAINT

Plaintiff K & S Associates, Inc. ("K&S"), hereby submits this Verified Complaint against Defendant, American Association of Physicists in Medicine ("AAPM"), and for its cause of action would show:

THE PARTIES

- 1. K&S is a Tennessee corporation having its principal place of business at 1926 Elm Tree Drive, Nashville, Davidson County, Tennessee 37210-3718.
- 2. On information and belief, AAPM is a Maryland corporation having its principal place of business at One Physics Ellipse, College Park, Maryland 27040.

SUBJECT MATTER JURISDICTION

3. This case arises under the antitrust laws of the United States; specifically, 15 U.S.C. §§ 1 and 26. Accordingly, jurisdiction is appropriate in this Court pursuant to 28 U.S.C. § 1331. Additionally, this Court has original jurisdiction over this antitrust action pursuant to 28 U.S.C. § 1337.

PERSONAL JURISDICTION

- 4. This Court has jurisdiction over any party over which the courts of general jurisdiction in the State of Tennessee could constitutionally exercise jurisdiction in accordance with Fed. R. Civ. P. 4(k)(1) and Tenn. Code Ann. § 20-2-225.
- 5. Defendant caused tortious antitrust injury in the State of Tennessee, and has engaged in a persistent course of conduct directed at Tennessee through its activities purporting to regulate K&S's activities in Tennessee. Moreover, agents of Defendant traveled to Tennessee to evaluate Plaintiff's work in April 2009 and have sent numerous communications to Plaintiff in Tennessee in the ordinary course of business over the years and, more recently, specifically related to the subject matter of this action. A copy of Defendant's June 12, 2009 "Final Surveillance Report" reflecting the AAPM's agents' visit to Tennessee for the purpose of evaluating K&S's reaccreditation is attached as Exhibit A. This action, in substantial part, arises out of Defendant's contacts with the State of Tennessee. Therefore, this Court has personal jurisdiction over AAPM.

VENUE

6. Plaintiff seeks injunctive relief under section 16 of the Clayton Act, 15 U.S.C. § 26. Venue for such actions is appropriate in "any court of the United States having jurisdiction over the parties[.]" *Id.* Because this Court has jurisdiction over the parties, as outlined above, venue is appropriate in this Court.

FACTS

7. Plaintiff, K&S, is one of three "Accredited Dosimetry Calibration Laboratories" ("ADCLs") in the United States. ADCLs calibrate a line of commercial products broadly classified as "dosimetry" equipment. Dosimetry equipment, generally speaking, is designed to

assess the extent to which biological tissue has absorbed radiation during the course of radiation therapy (which is primarily utilized for cancer treatment).

- 8. Defendant AAPM is a trade association which, *inter alia*, controls the accreditation process of ADCLs. The end users of dosimetry equipment in the medical community will not utilize the calibration services of any private laboratory unless that laboratory is accredited by the AAPM. No ADCLs currently operate in the United States without AAPM accreditation, and on information and belief, no ADCL *could* operate or maintain customers without AAPM accreditation. K&S has been an AAPM-accredited ADCL since 1982.
- 9. Under AAPM's procedures, an ADCL must ordinarily apply for re-accreditation to the Calibration Laboratory Accreditation Subcommittee ("CLA") every four years. (The CLA is a subcommittee of the Therapy Physics Committee ("TPC") of the AAPM.) The voting members of the CLA vote on the motion for re-accreditation. As K&S understands the process, the recommendation of the CLA is submitted directly to the Board of Directors of the AAPM for final action. However, in the event of a negative CLA recommendation, the affected ADCL may submit an appeal to the TPC prior to the taking of final action by the Board.
- 10. Additionally, re-approval of accreditation within the four-year period is required by a number of "triggering" events, including a change in the ownership of an ADCL.
- 11. It bears emphasis that as a matter of AAPM written policy, "[t]he AAPM will normally have no reason to consider revocation [of an ADCL] as long as the performance on proficiency tests are satisfactory and the procedures of the laboratory are in accordance with its protocol and its personnel or performance are not significantly changed."
- 12. Also, in addition to the four-year re-accreditation cycle, the CLA co-chairs conduct annual "surveillance visits" to each ADCL to evaluate it for continuing compliance with

AAPM accreditation criteria. Any reported negative event or unsatisfactory surveillance visit can trigger a re-examination of an ADCL's accreditation status with the AAPM. In the twenty-seven years that K&S has been an AAPM-accredited ADCL, it has never had a reported negative event or unsatisfactory surveillance visit.

- 13. The other two ADCLs in the country are the University of Wisconsin ADCL ("UW ADCL") and the M.D. Anderson Cancer Center ADCL, which is affiliated with the University of Texas-Houston.
- 14. The director of the UW ADCL is an individual named Dr. Larry DeWerd. Dr. DeWerd also holds an ownership interest in Standard Imaging, Inc., a Wisconsin corporation that manufactures dosimetry equipment.
 - 15. The director of the M.D. Anderson Cancer Center ADCL is Dr. Geoffrey Ibbott.
- 16. In the latter part of 2008, K&S entered into a conditional agreement with a German manufacturer of dosimetry equipment, Physikalisch-Technische Werkstaetten Dr. Pychlau GmbH ("PTW-Freiburg") (a competitor of Standard Imaging, Inc.), for the purchase of K&S's stock. Given the parties' knowledge that PTW-Freiburg's acquisition of K&S would automatically require K&S to be evaluated for re-accreditation by the AAPM, an essential predicate for the sale was the AAPM's continued accreditation of K&S.
- 17. In a good faith effort to confront and avoid any conceivable conflict of interest issues, real or perceived, at the front end, K&S (in the person of Tom Slowey, its President) contacted Dr. Jan Seuntjens and Dr. Malcolm McEwen, co-chairs of the CLA, concerning the proposed sale. In the communications that ensued, Mr. Slowey sought Dr. Seuntjens's "recommendations" for any needed changes in K&S's policies and procedures to insure compliance with Sections 4.1.4 and 4.1.5 of the AAPM's July 2006 "Criteria for Accreditation of

Dosimetry Calibration Laboratories" (concerning conflicts of interest specifically). A copy of Mr. Slowey's initial letter on the subject (dated August 29, 2008) is attached as Exhibit B.

- 18. Dr. Seuntjens promptly responded by way of a letter dated September 4, 2008 (Exhibit C). He raised four specific points for K&S to address concerning the potential conflict of interest issue. Mr. Slowey responded item-by-item in his letter of September 9, 2008 (Exhibit D). This letter specifically stated that "PTW may, from time to time, have promotions for instruments that include a K&S ADCL calibration." In other words, Mr. Slowey went out of his way to disclose, in good faith, the expectation that PTW would run advertisements that offered K&S calibrations. The CLA (through its Chair) did not express any disapproval of this concept.
- 19. In an email the next day (which copied CLA Co-Chair Malcolm McEwen), Dr. Seuntjens thanked Mr. Slowey for his prompt reply and specifically stated that it "adequately addresses our questions." (A copy of the pertinent email "chain" is attached as Exhibit E.) He further observed that there would be a "surveillance visit" in April of 2009 "sometime after the acquisition by PTW has been completed," and Dr. Seuntjens closed by formally taking this "opportunity to thank you and K&S again for the excellent service to the AAPM community for nearly three decades."
- 20. In a responsive email on September 16, 2008 (Exhibit F), Mr. Slowey sought a clarification of a statement that had appeared in Dr. Seuntjens's September 10 communication (Exhibit E), conveying that "[t]he accreditation status [of K&S] will stay the same and as long as the conflict of interest issue is addressed satisfactorily, continued accreditation until the next surveillance visit can be maintained." Mr. Slowey specifically wanted to confirm that "the ongoing AAPM status of K&S will be maintained as long as the conflict of interest issue is satisfactorily addressed with the new ownership" (not just until the upcoming surveillance visit),

while recognizing that "[i]f the assessment team finds that any of our policies and procedures are not adequate, it is our intent [to] modify them to the satisfaction of the assessment team."

- 21. In a September 18, 2008 email two days later (Exhibit G), Dr. Seuntjens confirmed that his earlier statement should have read instead that: "The accreditation status will stay the same and as long as the conflict of interest issue is addressed satisfactorily, continued accreditation can be maintained." This constitutes an unambiguous acknowledgment that mere ownership by a manufacturer did not, by itself, give rise to a forbidden conflict of interest, because it was subject to being "addressed satisfactorily." Dr. Seuntjens further observed that the prospective surveillance visit (in April 2009) would provide an opportunity to evaluate the managerial structure and insure that it was satisfactory with respect to the concern about conflict of interest.
- 22. K&S drafted a set of proposed conflict-of-interest policies and procedures, and sent these to Drs. Seuntjens and McEwen by way of a November 20, 2008 email (Exhibit H). This email specifically sought the review of the CLA Co-Chairs and any suggested changes. The only suggestion that the CLA Co-Chairs offered (conveyed by telephone, to the best of our knowledge) was to recommend the modification of paragraph 4 on page 2 to *allow* laboratory staff to give advice about instrument performance to customers, subject to certain conditions. Comparison of the final version of the policy (Exhibit I) with the draft (Exhibit H) demonstrates that K&S's own draft had actually been more restrictive, prohibiting laboratory personnel from giving *any* advice about dosimetry instruments to customers.
- 23. On January 16, 2009, PTW's acquisition of K&S's stock was consummated, effective Jan. 1, 2009.

- 24. In April 2009, the CLA co-chairs paid the planned "surveillance visit" to K&S in Nashville pursuant to the automatic re-accreditation requirement that PTW-Freiburg's acquisition of K&S had triggered, primarily to assess the implementation of the conflict-of-interest policies and procedures. The CLA Co-Chairs prepared a report of this visit reflecting that they had thoroughly assessed the conflict of interest issue, and concluding that the AAPM's requirements concerning conflicts of interest "are being met," while also recognizing that the "issue of conflict of interest will need to be reviewed on a regular basis to insure continued compliance." In their conclusion, the Co-Chairs recommended re-accreditation of K&S under the new ownership of PTW-Freiburg. A copy of the "Final Surveillance Report" has been previously attached as Exhibit A. The Final Report's recommendation was to be presented to the CLA for the review and vote of its members at its scheduled meeting in July.
- 25. In the meantime, on a visit to K&S in early July 2009, Dr. Christian Pychlau (PTW-Freiburg's principal and co-owner) mentioned to Mr. Slowey that he had received some email correspondence from Dr. Seuntjens (dated May 5), who expressed a "major concern" about a flyer distributed by PTW-NY (a United States subsidiary of PTW-Freiburg), which advertised K&S calibration in conjunction with PTW dosimetry equipment. A copy of this flyer is attached as Exhibit J. After he returned to Germany, Dr. Pychlau forwarded to Mr. Slowey the series of email communications between Dr. Seuntjens and Dr. Pychlau that had passed between them in early May. Copies are attached as Exhibit K.
- 26. Notably, while stating that he did not believe the ad violated any AAPM rules or criteria, Dr. Pychlau both apologized if the ad had offended the AAPM and offered to make sure that it never happened again, if such was the AAPM's wish. Dr. Seuntjens did not respond to the offer. The "major concern" letter from Dr. Seuntjens to Dr. Pychlau was dated May 5; the Final

Report of the site visit was dated June 12. Given this chronology, it is at least surprising that the Final Report from the site visit said nothing about the advertisement in its "Conflict of Interest" discussion.

- 27. This news prompted Mr. Slowey to do some research on AAPM's Web site, where he discovered a CLA sub-committee report to the TPC that Dr. Seuntjens himself had submitted on April 7, 2009 (Exhibit L). The report noted that K&S had been acquired by PTW, and that CLA management had received "[l]etters of protest" from the University of Wisconsin "board" and from an unnamed "competing ion chamber manufacturer." On information and belief, this "competing ion chamber manufacturer" was Standard Imaging. In other words, competitors of K&S and PTW-Freiburg sought to use the CLA to harm K&S's competitive position in the marketplace.
- 28. Dr. Pychlau subsequently provided proof to Dr. Seuntjens in a series of communications that Standard Imaging advertised in conjunction with the UW ADCL. A copy of a sampling of these advertisements is attached as Exhibit S. K&S further pointed out the widely-known synergy between the UW ADCL and Standard Imaging, facilitated by Dr. DeWerd's position with both entities, to wit:
 - a. The UW ADCL receives substantial business from Standard Imaging sales of instruments and Standard Imaging's promotion of UW ADCL's services (in a manner materially indistinguishable from the flyer that drew objection from K&S's competitors); and
 - b. Dr. DeWerd is both the director of the UW ADCL and also a part owner of Standard Imaging.

- c. To the best of K&S's knowledge, the CLA has to this point simply accepted Dr. DeWerd's bald assertion that he has no conflict of interest based on these facts, and has not even suggested that conflict of interest procedures be implemented at the UW ADCL.
- 29. In what was presented as an effort to harmonize the relationships between and among the ADCLs, a "conflict of interest roundtable" was scheduled for July 25, 2009, ostensibly to reach a compromise on conflict of interest policies and procedures that would be applicable to all three ADCLs. Present at this meeting were Angela Keyser (AAPM Executive Director), Jerry White (AAPM's Chairman of the Board), Steve Seltzer (a representative from the NIST), Jan Seuntjens (CLA chair), Malcolm McEwen (CLA co-chair), Geoff Ibbott (of the M.D. Anderson Cancer Center at UT-Houston), Larry DeWerd (director of the UW ADCL and part-owner of Standard Imaging, a competitor of PTW-Freiburg), and Thomas Slowey of K&S.
- 30. Almost immediately, however, the discussion turned to the issue of whether PTW-Freiburg's ownership of K&S was "acceptable" to the UW ADCL and the M.D. Anderson Cancer Center ADCL (K&S's only two competitors). On behalf of the UW ADCL and the M.D. Anderson Cancer Center ADCL, respectively, Dr. DeWerd and Dr. Ibbott flatly stated that PTW-Freiburg's ownership was unacceptable to them, notwithstanding *any* conflict of interest procedures that might be put into place. In other words, K&S's direct competitors were permitted to directly influence the decision as to whether K&S should be permitted to continue to operate as an ADCL. The upshot of the meeting was that the voting membership of the CLA was pressured to vote against re-accrediting K&S in the meeting of that body that followed shortly thereafter the same day, notwithstanding the favorable recommendation for re-

accreditation that K&S had received from the CLA co-chairs who had specifically considered the conflict of interest issue.

- 31. As just stated, the voting membership of the CLA met later that day and rejected the motion submitted by the CLA co-chairs to recommend the re-accreditation of K&S as an AAPM ADCL. A copy of the July 27 letter informing K&S of the CLA's decision is attached as Exhibit M. K&S was informed by counsel for the AAPM that an appeal could be directed to the Therapy Physics Committee ("TPC") of the AAPM, but was not informed of any reason or basis for the CLA's decision, was not given any evidence considered by the CLA, or a copy of the minutes of the CLA's meeting. A copy of the September 1, 2009 letter from counsel for AAPM is attached as Exhibit N. In other words, K&S was forced to appeal a decision without knowing what it had been based upon.
- 32. Notwithstanding these difficulties, counsel for K&S attempted in good faith to submit an appellate brief (attached as Exhibit O, less its Exhibits) to the TPC based upon the assumption that the CLA had rejected K&S's re-accreditation based upon (pretextual) conflict of interest concerns. K&S submitted its appellate brief to the TPC on October 30. To date, K&S has received no response to the appeal, and in fact has been informed that the TPC may send the matter on to the board of directors of the AAPM for final action prior to the time that K&S is notified of the TPC's decision concerning the appeal. Under that scenario, the appeal process would be meaningless.
- 33. Before submitting this brief, counsel for K&S attempted repeatedly to inquire of counsel for AAPM concerning the time frame in which the appeal would be adjudicated, whether K&S would have the opportunity to appear and be heard, and whether there would be an interval

between the decision of the TPC and any final action by the board. A series of letters and emails that counsel for K&S sent to counsel for AAPM is attached as Exhibit P.

- 34. The only substantive response that counsel for AAPM ever provided came by way of a letter dated October 13, 2009 (Exhibit Q). This October 13 letter stated that the Board of Directors of AAPM will consider the matter on November 28, 2009. However, counsel also conveyed that the board might meet electronically on some other, unspecified date. (The letter does not specify whether this date would be before or after November 28.) The letter declined to provide further information and, indeed, left the unmistakable impression that all scheduling matters were indefinite and up in the air (at least insofar as any notice to K&S was concerned).
- 35. The AAPM has flatly refused to provide any other response to K&S's eminently reasonable requests for information, or to produce any documents or other evidence that the CLA considered or that the TPC or Board of Directors might consider.
- 36. On Nov. 2, undersigned counsel for K&S sent a letter (Exhibit R) to counsel for AAPM that specifically raised the issue of whether AAPM was engaged in an antitrust conspiracy against K&S, and pleading again for a prompt response to its requests for further information. To date, the AAPM has provided no response to this letter.

COUNT I – INJUNCTIVE RELIEF UNDER § 16 OF THE CLAYTON ACT

- 37. Paragraphs 1 through 36 are hereby incorporated by reference as if set forth fully herein.
- 38. Any private party "shall be entitled to sue for and have injunctive relief . . . against threatened loss or damage by a violation of the antitrust laws[.]" 15 U.S.C. § 26 ("The Clayton Act § 16"). Under the antitrust laws, any conspiracy in restraint of trade is illegal. 15 U.S.C. § 1 ("The Sherman Act § 1"). If the AAPM, acting through its employees, agents,

servants, apparent agents, and co-conspirators, refuses to re-approve the accreditation of K&S based upon facts set forth above, it will constitute a concerted refusal to deal, which is *per se* illegal under the Sherman Act § 1.

- 39. Specifically, as set forth above, the AAPM engaged in a conspiracy with the competitors of K&S and PTW-Freiburg, including but not necessarily limited to Standard Imaging, the UW ADCL, the M.D. Anderson Cancer Center ADCL, and Dr. DeWerd, to orchestrate a concerted refusal to deal with K&S.
- 40. K&S faces an immediate threat of irreparable harm if AAPM refuses to reapprove K&S as an ADCL, in violation of the Sherman Act § 1. The equities of this case demand the conclusion that K&S is entitled to a Temporary Restraining Order and, upon a hearing, a Preliminary Injunction, to prevent the threatened loss caused by the AAPM's actions in violation of the antitrust laws, all as more fully set forth in the Memorandum of Law filed in support of Plaintiff's Motion for a Temporary Restraining Order and Preliminary Injunction.

WHEREFORE, PREMISES CONSIDERED, K&S requests relief as follows:

- 1. That this Court issue the proposed Temporary Restraining Order submitted contemporaneously with this Verified Complaint;
 - 2. A hearing on Plaintiff's motion for a Preliminary Injunction;
- 3. Upon that hearing, the issuance a Preliminary Injunction prohibiting further violations of the Sherman Act § 1, specifically including, but not limited to, the removal of K&S's accreditation;
- 4. The waiver of an injunction bond because AAPM will not be harmed by the issuance of the requested injunctive relief; and
 - 5. Such other relief as the Court may deem just and proper.

Respectfully Submitted,

NEAL & HARWELL, PLC

By: /s/ Aubrey B. Harwell, Jr.
Aubrey B. Harwell, Jr., #002559
James G. Thomas, #007028
Leon H. Wolf, #027638

Attorneys for Plaintiff, K & S Associates, Inc.

VERIFICATION

STATE OF TENNESSEE)
COUNTY OF DAVIDSON)

Thomas W. Slowey, being first duly sworn, deposes and states that he is the President of Plaintiff, K & S Associates, Inc., and that he has read the foregoing Complaint (including its Exhibits) and is familiar with the contents thereof; that the factual allegations contained therein are true of his own knowledge, except as to those matters therein stated to be alleged on information and belief, and as to those matters, he believes them to be true; and that he makes this affidavit on behalf of K & S Associates, Inc.

K & S ASSOCIATES, INC.

Thomas W. Slove

President

Sworn to me and subscribed before me this 18th day of November, 2009.

Notary Public

THRAILKILL, HARRIS, WOOD & BOSWELL, PLC

By: /s/ Christopher Harris

Christopher Harris, #005640

5141 Virginia Way, Suite 240 P.O. Box 2048 Brentwood, TN 37024-2408

CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing has been served upon the following counsel for Defendant by e-mail, facsimile, and Federal Express, this the 18th day of November, 2009:

Murray E. Bevan, Esq. Bevan, Mosca, Guiditta & Zarillo, PC 776 Mountain Blvd., Suite 202 Watchung, NJ 07069

/s/ Aubrey B. Harwell, Jr.